STOOL SOFTENER- docusate sodium capsule, liquid filled
DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DOCUSATE SODIUM

Docusate Sodium 100 mg

Stool Softener Laxative

relieves occasional constipation (irregularity)

generally produces bowel movement in 12 to 72 hours

Ask a doctor before use if you

• have stomach pain, nausea or vomiting

• have a sudden change in bowel habits that persists over a period of 2 weeks

• are presently taking mineral oil

Stop use and ask a doctor if

• you need to use a laxative longer than 1 week

• you have rectal bleeding or fail to have a bowel movement. These

could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

• adults and children 12 years and older: take 1-2 softgel daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor

• children under 12: consult a doctor

• do not exceed recommended dose

• each softgel contains: sodium 5 mg. very low sodium

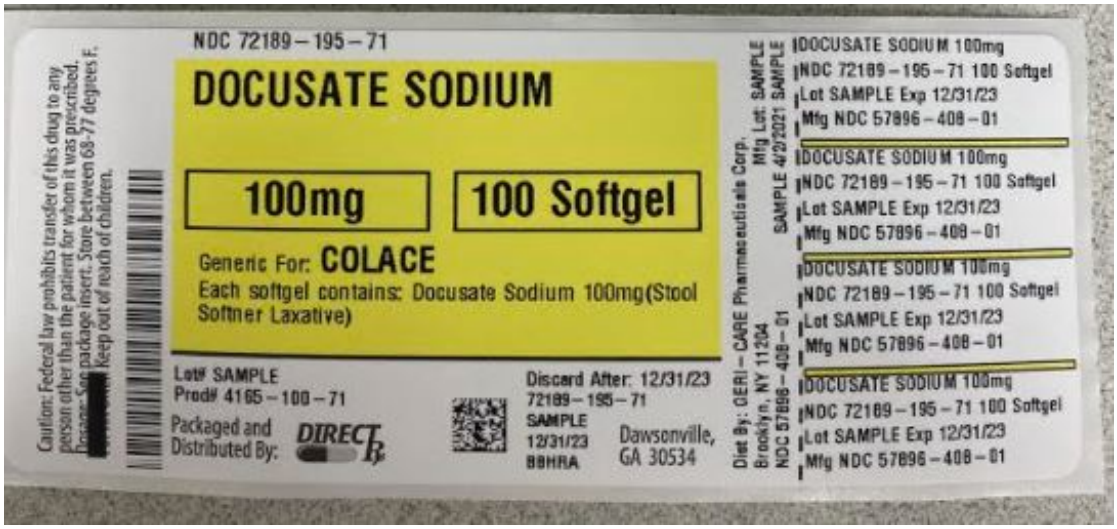
• store at 15°C-25°C(59° F-77° F)

• keep tightly closed

• product from USA or Canada

• Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

FD&C red #40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. Also contains D&C yellow #10
or FD&C yellow #6 (sunset yellow).



STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72189-195(NDC:57896-408)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	A92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-195-71	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/30/2021	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(72189-195)

Revised: 4/2021 DIRECT RX